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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,522	09/22/2003	Andre Stamm	31672-224622	5813

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EXAMINER	
SHEIKH, HUMERA N	

ART UNIT	PAPER NUMBER
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/665,522	STAMM ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 September 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6,7,13,14,16,18-20,25-33,36,38,39 and 41-48* is/are pending in the application.

4a) Of the above claim(s) *6,7,13,14,25-33,38,39 and 46-48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16,18-20,36 and 41-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt is acknowledged of the Request for Continued Examination (RCE) under 37 C.F.R. 1.114, the Amendment and Applicant's Arguments/Remarks, all filed 09/15/10. The Response/Amendment has been entered.

Applicant has overcome the 35 U.S.C. 112, second paragraph rejection of claims 16 and 42 by virtue of the amendment to the claims. Accordingly, the 35 U.S.C. 112, second paragraph rejection has been withdrawn.

Claims 6, 7, 13, 14, 16, 18-20, 25-33, 36, 38-39 and 41-48 are pending in this action. Claims 16 and 42 have been amended. Claims 6, 7, 13, 14, 25-33, 38, 39 and 46-48 remain withdrawn from consideration (based on non-elected invention - see Response to Restriction filed 09/06/06). Claims 1-5, 8-12, 15, 17, 21-24, 34, 35, 37 and 40 have previously been cancelled. Claims 16, 18-20, 36 and 41-45 are currently under consideration. Claims 16, 18-20, 36 and 41-45 are rejected.

* * * * *

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 15 September 2010 has been entered.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 16, 18-20, 36 and 41-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krause (U.S. Pat. No. 4,859,703) in view of Deboeck et al. (hereinafter "Deboeck") (U.S. Pat. No. 5, 545,628).

Krause ('703) teaches single dose formulations containing a combination of a lipid regulating agent selected from gemfibrozil, clofibrate, bezafibrate or fenofibrate and an ACAT inhibiting agent that are effective pharmaceutical formulations for regulating blood serum lipid and cholesterol levels (see Abstract); (col. 2, lines 12-22); (col. 4, lines 15-19).

Oral administration forms taught include tablets, as well as capsules, powders and sachets (col. 5, lines 12-20). Powders and tablets contain between about 5 to about 70% by weight of the active ingredient.

The pharmaceutical preparations can be in unit dosage forms (col. 5, lines 36-44).

In therapeutic use, as hypolipidemic or hypcholesterolemic agents, the pharmaceutical compositions are administered to the patient at dosage levels of from 300 to 1200 mg per day of the lipid regulating agent, which can be selected from among others, fenofibrate (col. 5, lines 45-58).

Examples 5-10 at columns 7-9 demonstrate various immediate release tablet formulations comprising a lipid regulating agent selected from gemfibrozil, clofibrate, bezafibrate and fenofibrate. Example 5, for instance presents an immediate release tablet formulation containing 300 mg of lipid regulating agent chosen from gemfibrozil, clofibrate, bezafibrate and fenofibrate. Similarly, Example 6 demonstrates an immediate release tablet formulation containing 450 mg of lipid regulating agent.

Krause teaches that the pharmaceutical compositions are administered at dosage levels of from 300 to 1200 mg per day of the lipid regulating agent, such as for instance, fenofibrate (col. 5, lines 45-58).

Krause does not teach fenofibrate to be provided in a daily dose lower than 200 mg.

Deboeck et al. ('628) teach a pharmaceutical composition provided for treating hyperlipidemia or hypercholesterolemia or both, which contains an effective amount of fenofibrate and an excipient (see Abstract); (col. 1, line 6 - col. 2, line 67).

Deboeck teaches that generally, the effective daily amount of fenofibrate for humans ranges from about 100 mg to 600 mg per day, and preferably from about 100 to 300 mg per day (col. 8, lines 18-24); and Claim 12. Also see col. 4, lines 51-63 and col. 7, lines 57-67. This amount/range meets Applicants claimed amount of a daily dose of lower than 200 mg as recited in instant claim 16. These amounts are used to advantageously treat hyperlipidemia or hypercholesterolemia (col. 8, lines 18-20).

Deboeck also teaches that the compositions contain from about 5% to 95% by weight of fenofibrate (col. 3, lines 49-58). Moreover, with regards to amounts and/or ranges, the Examiner points out that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

The pharmaceutical compositions offer increased bioavailability of the fenofibrate as compared to conventional formulations (col. 3, lines 36-38).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a fenofibrate formulation that comprises a daily effective amount of fenofibrate in amounts lower than 200 mg, such as about 100 mg as taught by Deboeck within the lipid formulations of Krause. One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Deboeck explicitly teaches fenofibrate pharmaceutical compositions whereby the daily effective amount of fenofibrate for humans ranges from about 100 mg to 600 mg per day

and Deboeck teaches that these amounts are used in order to advantageously and effectively treat hyperlipidemia or hypercholesterolemia. The expected result would be an improved fenofibrate formulation that has increased bioavailability for the beneficial treatment of hyperlipidemic and high cholesterol conditions.

Regarding the claim 16 and 42 limitations of "bioavailability being greater than that of Lipanthyl®200M" this limitation does not impart patentability to the present claims. Example 3 on page 12 of the specification indicates that the enhanced bioavailability occurs as a result of the specific bioavailability parameters (AUC, Cmax, T_{max}). However, the instant claims are entirely generic in this regard. The instant claims do not introduce any specific dissolution profiles, rates of release, nor any specific AUC, Cmax, T_{max} levels, which would distinguish over the teachings of the prior art. The claims are silent in terms of these specific features. Thus, the limitation does not define over the prior art disclosure. The instant claims are generic in scope as compared to that with the particular examples (i.e., Example 3) of the specification.

Regarding claims 41-45, which recite a fenofibrate tablet wherein the 'bioavailability is assessed by AUC, Cmax or both', it is the position of the Examiner that this limitation is met by the combination teachings of the prior art. The prior art explicitly teaches fenofibrate formulations having increased bioavailability of fenofibrate as compared to conventional formulations. See for instance, Deboeck col. 3, lines 36-38. The art further teaches bioavailability parameters (AUC, Cmax, T_{max}) and teaches suitable bioavailability levels (see Table 4 of Deboeck at column 8). The manner by which the bioavailability of fenofibrate is assessed does not impart patentability to the claims since the art clearly recognizes fenofibrate formulations that exhibit increased or

improved bioavailability. Moreover, a product is being claimed herein and not a method of assessing bioavailability of an active ingredient. It is the patentability of the product that must be established and not the manner by which bioavailability is achieved or assessed. Furthermore, Applicant credits the improved bioavailability of their composition based on their fenofibrate processing techniques. It is noted that the instant claims are drawn to a product and not a process of manufacturing fenofibrate. In any event, the prior art teaches fenofibrate products having increased or improved bioavailability. The art further recognizes using low dosage of fenofibrate (200 mg) to achieve therapeutic effects (i.e., bioavailability).

* * * * *

Claims 16, 18-20, 36 and 41-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ghebre-Sellassie et al. (hereinafter "Ghebre-Sellassie") (U.S. Pat. No. 4,927,639) in view of Krause (U.S. Pat. No. 4,859,703) and further in view of Deboeck et al. (hereinafter "Deboeck") (U.S. Pat. No. 5, 545,628).

Ghebre-Sellassie et al. ('639) teach a disintegratable formulation of gemfibrozil providing both immediate and sustained release and comprises a tablet compressed from a mixture of a first and second granulation and a disintegration excipient (see Abstract); (col. 1, lines 9-15; 60-68); (col. 2, lines 63-64).

Ghebre-Sellassie teaches gemfibrozil, a widely used antihyperlipoproteinemic agent (col. 1, lines 9-15).

Ghebre-Sellassie does not teach fenofibrate.

Krause ('703) teaches single dose formulations containing a combination of a lipid regulating agent selected from gemfibrozil, clofibrate, bezafibrate or fenofibrate and an ACAT inhibiting agent that are effective pharmaceutical formulations for regulating blood serum lipid and cholesterol levels (see Abstract); (col. 2, lines 12-22); (col. 4, lines 15-19).

Oral administration forms taught include tablets, as well as capsules, powders and sachets (col. 5, lines 12-20). Powders and tablets contain between about 5 to about 70% by weight of the active ingredient.

The pharmaceutical preparations can be in unit dosage forms (col. 5, lines 36-44).

In therapeutic use, as hypolipidemic or hypcholesterolemic agents, the pharmaceutical compositions are administered to the patient at dosage levels of from 300 to 1200 mg per day of the lipid regulating agent, which can be selected from among others, fenofibrate (col. 5, lines 45-58).

Examples 5-10 at columns 7-9 demonstrate various immediate release tablet formulations comprising a lipid regulating agent selected from gemfibrozil, clofibrate, bezafibrate and fenofibrate. Example 5, for instance presents an immediate release tablet formulation containing 300 mg of lipid regulating agent chosen from gemfibrozil, clofibrate, bezafibrate and fenofibrate. Similarly, Example 6 demonstrates an immediate release tablet formulation containing 450 mg of lipid regulating agent.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate any lipid regulating agent, particularly fenofibrate, as taught by Krause within the lipid composition of Ghebre-Sellassie. One of ordinary skill in the art

would be motivated to do so with a reasonable expectation of success because Krause explicitly teaches single dose formulations containing a combination of a lipid regulating agent that can be selected from gemfibrozil, clofibrate, bezafibrate or fenofibrate and teach that such lipidemic agents are effective for regulating blood serum lipid and cholesterol levels. The expected result would be an enhanced fenofibrate composition that exhibits increased bioavailability and effective treatment of hyperlipidemia and hypercholesterolemia.

The teachings of Ghebre-Sellassie and Krause are delineated above. They do not teach fenofibrate to be provided in a daily dose lower than 200 mg.

Deboeck et al. ('628) teach a pharmaceutical composition provided for treating hyperlipidemia or hypercholesterolemia or both, which contains an effective amount of fenofibrate and an excipient (see Abstract); (col. 1, line 6 - col. 2, line 67).

Deboeck teaches that generally, the effective daily amount of fenofibrate for humans ranges from about 100 mg to 600 mg per day, and preferably from about 100 to 300 mg per day (col. 8, lines 18-24); and Claim 12. Also see col. 4, lines 51-63 and col. 7, lines 57-67. This amount/range meets Applicants claimed amount of a daily dose of lower than 200 mg as recited in instant claim 16. These amounts are used to advantageously treat hyperlipidemia or hypercholesterolemia (col. 8, lines 18-20).

Deboeck also teaches that the compositions contain from about 5% to 95% by weight of fenofibrate (col. 3, lines 49-58). Moreover, with regards to amounts and/or ranges, the Examiner points out that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are

disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

The pharmaceutical compositions offer increased bioavailability of the fenofibrate as compared to conventional formulations (col. 3, lines 36-38).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a fenofibrate formulation that comprises a daily effective amount of fenofibrate in amounts lower than 200 mg, such as about 100 mg as taught by Deboeck within the lipid formulations of Ghebre-Sellassie and alternatively, Krause. One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Deboeck explicitly teaches fenofibrate pharmaceutical compositions whereby the daily effective amount of fenofibrate for humans ranges from about 100 mg to 600 mg per day and Deboeck teaches that these amounts are used in order to advantageously and effectively treat hyperlipidemia or hypercholesterolemia. The expected result would be an improved fenofibrate formulation that has increased bioavailability for the beneficial treatment of hyperlipidemic and high cholesterol diseases.

Regarding the claim 16 and 42 limitations of "bioavailability being greater than that of Lipanthyl®200M" this limitation does not impart patentability to the present claims. Example 3 on page 12 of the specification indicates that the enhanced bioavailability occurs as a result of the specific bioavailability parameters (AUC, Cmax, T_{max}). However, the instant claims are entirely generic in this regard. The instant claims do not introduce any specific dissolution profiles, rates of release, nor any specific AUC,

Cmax, T_{max} levels, which would distinguish over the teachings of the prior art. The claims are silent in terms of these specific features. Thus, the limitation does not define over the prior art disclosure. The instant claims are generic in scope as compared to that with the particular examples (i.e., Example 3) of the specification.

Regarding claims 41-45, which recite a fenofibrate tablet wherein the 'bioavailability is assessed by AUC, Cmax or both', it is the position of the Examiner that this limitation is met by the combination teachings of the prior art. The prior art explicitly teaches fenofibrate formulations having increased bioavailability of fenofibrate as compared to conventional formulations. See for instance, Deboeck col. 3, lines 36-38. The art further teaches bioavailability parameters (AUC, Cmax, T_{max}) and teaches suitable bioavailability levels (see Table 4 of Deboeck at column 8). The manner by which the bioavailability of fenofibrate is assessed does not impart patentability to the claims since the art clearly recognizes fenofibrate formulations that exhibit increased or improved bioavailability. Moreover, a product is being claimed herein and not a method of assessing bioavailability of an active ingredient. It is the patentability of the product that must be established and not the manner by which bioavailability is achieved or assessed. Furthermore, Applicant credits the improved bioavailability of their composition based on their fenofibrate processing techniques. It is noted that the instant claims are drawn to a product and not a process of manufacturing fenofibrate. In any event, the prior art teaches fenofibrate products having increased or improved bioavailability. The art further recognizes using low dosage of fenofibrate (200 mg) to achieve therapeutic effects (i.e., bioavailability).

* * * * *

Response to Arguments

Applicant's arguments filed 15 September 2010 have been fully considered and were found to be partially persuasive.

- **Claim Rejections - 35 USC § 112:**

Applicant stated, "The claims have been amended to overcome the 35 U.S.C. 112, second paragraph rejections. Trademarked composition names have been deleted and a generic description provided."

This argument was persuasive by virtue of the amendment to the claims 16 and 42. Accordingly, the 35 U.S.C. 112, second paragraph rejections have been withdrawn.

The Invention:

Applicant argues that their "improved bioavailability of their composition is based on a novel process" or their fenofibrate processing techniques. Namely, Applicant argues that their fluid-bed granulation techniques attribute to enhanced bioavailability of the formulation. This argument was not deemed persuasive. The instant claims are drawn to a fenofibrate product and not a process of manufacturing fenofibrate. It is the patentability of the product that must be established and not the manner by which bioavailability is achieved (such as by specific manufacturing processes – i.e.., fluid bed granulation). Thus, Applicant's arguments drawn to the advantages of the manufacturing process are not commensurate in scope with the instant product claims. In any event, the prior art teaches fenofibrate products having increased or improved bioavailability. The art further recognizes using low dosage of fenofibrate (200 mg) to achieve therapeutic effects (i.e., bioavailability).

- **Rejection under 35 U.S.C. §103(a) over Krause (US'703) and Deboeck (US '628); and Ghebre-Sellassie (US '639) in view of Krause and Deboeck:**

Applicant argues, "Krause compositions may comprise from 300 to 1200 mg of fenofibrate. Krause tablets should be bioequivalent to Lipanthyl®300, the first generation of fenofibrate drugs. Krause tablets are not bioequivalent to Lipanthyl®200M, let alone superior to them."

This argument was not found persuasive. While it is noted that the Krause compositions may comprise from 300 to 1200 mg of fenofibrate, and not a daily dose of 'lower than 200 mg', the secondary reference of Deboeck was relied upon for the teaching of fenofibrate compositions whereby the fenofibrate ranges from about 100 mg to 600 mg per day, and preferably from about 100 to 300 mg per day (see col. 8, lines 18-24). Deboeck further teaches that their pharmaceutical compositions offer increased bioavailability of the fenofibrate as compared to conventional formulations (col. 3, lines 36-38). Thus, Deboeck was invoked for and amply demonstrates using lower dosages of fenofibrate to obtain therapeutic and beneficial results, such as enhanced bioavailability. There is no patentability seen in Applicant's limitation of "wherein the bioavailability is greater than that of Lipanthyl®200M", since the prior art vividly teaches fenofibrate compositions having improved bioavailability; the same objective as that desired by Applicant.

Regarding the rejection of Ghebre-Sellassie (US '639) in view of Krause and Deboeck, Applicant argued, "Ghebre-Sellassie is directed to gemfibrozil, where the tablet

has both an immediate release part and a sustained release part in it, obtained by two different granulations".

Applicant's arguments have been considered but were not found persuasive. Admittedly, while Ghebre-Sellassie is directed to gemfibrozil, the secondary reference of Krause was relied upon for the teaching of compositions comprising fenofibrate or alternatively gemfibrozil. The argument that Ghebre-Sellassie's tablet has both an immediate release part and a sustained release part in it was not convincing, since the instant claims do not exclude the sustained release portion of Ghebre-Sellassie. The instant claims permit the controlled release portion of the prior art.

Regarding Deboeck, Applicant argued, "Deboeck is directed to fenofibrate composition, specifically to a generic of Lipanthyl®200M". Thus, Deboeck discloses a composition having the same bioavailability as Lipanthyl®200M". Deboeck is directed to capsules and not to a tablet."

These arguments were not deemed persuasive. Deboeck explicitly teaches fenofibrate formulations having increased bioavailability of fenofibrate as compared to conventional formulations. See for instance, Deboeck col. 3, lines 36-38. The art further teaches bioavailability parameters (AUC, Cmax, T_{max}) and teaches suitable bioavailability levels as that instantly desired by Applicant (see Table 4 of Deboeck at column 8). It is noted that Deboeck is drawn to fenofibrate capsules and not tablets. However, the primary reference of Krause initially recognizes and teaches various forms of fenofibrate formulations, including both capsules and tablets. See col. 5, lines 12-20 of Krause. Thus, the art is aware of the array of dosage forms available, particularly tablets.

Lastly, Applicant argued, "The invention is directed to a composition which has a bioavailability that is greater than that of Lipanthyl®200M. Krause and Ghebre-Sellassie provide tablets having a bioavailability that is lesser than that of Lipanthyl®200M. Deboeck provides capsules having the same bioavailability as Lipanthyl®200M. Thus, none of the documents, either individually or in combination render the instant invention obvious."

Applicant's arguments were not held persuasive. Applicant attributes improved bioavailability of their composition based on their process of manufacturing fenofibrate and directs the Examiner to Table 3 of the specification and Figure 1. The argument of improved bioavailability over that of Lipanthyl®200M was not convincing since the claims are generic in scope as compared to that with the particular examples of the specification. The enhanced bioavailability particularly of Example 3 on page 12 occurs as a result of the specific bioavailability parameters (AUC, Cmax, T_{max}). However, the instant claims are entirely generic in this regard. The instant claims do not introduce any specific dissolution profiles, rates of release, nor any specific AUC, Cmax, T_{max} levels, which would distinguish over the teachings of the prior art. The claims are silent in terms of these specific features. Thus, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., improved bioavailability as a result of the specific AUC, Cmax, T_{max}) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The art in combination achieves fenofibrate formulations having increased bioavailability, which is

the same objective sought herein by Applicant. For these reasons, Applicant's arguments remain unpersuasive.

Lastly, Applicant argued, "The Guichard document should be considered. Surprisingly, the invention demonstrates that it is further possible to increase the bioavailability of fenofibrate compositions".

This argument was not held persuasive. The art in combination achieves fenofibrate formulations having increased bioavailability, which is the same objective sought herein by Applicant. As a result, the teachings of the prior art in combination, are sufficient to render the instant invention prima facie obvious to one of ordinary skill in the art.

The 103(a) rejections of record have been maintained.

Conclusion

--No claims are allowed at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday-Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Humera N. Sheikh/
Primary Examiner, Art Unit 1615

hns
December 20, 2010